

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESale PRICE  
LITIGATION

THIS DOCUMENT RELATES TO:  
*State of Iowa v. Abbott Laboratories, et al.*

MDL No. 1456  
Master File No.: 01-CV-12257-PBS  
(original S. D. Iowa No. 4:07-cv-00461-  
JAJ-CFB)

Judge Patti B. Saris

**ANSWER AND AFFIRMATIVE DEFENSES OF PUREPAC  
PHARMACEUTICAL CO. TO THE STATE OF IOWA’S COMPLAINT**

Defendant Purepac Pharmaceutical Co. (“Purepac”),<sup>1</sup> by and through its attorneys, hereby states as an Answer and Affirmative Defenses to the State of Iowa’s Complaint, dated October 9, 2007, as follows:

**PRELIMINARY STATEMENT**

The State of Iowa’s Complaint (the “Complaint”) improperly refers to Purepac, other Defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against Purepac. This is insufficient to apprise Purepac of the allegations asserted against it. Purepac has nevertheless attempted to respond to Plaintiff’s allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, Purepac is generally without knowledge or information sufficient to form a belief as to the truth of those allegations. Purepac states

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<sup>1</sup> This Answer is submitted solely on behalf of Defendant Purepac Pharmaceutical Co. Defendant Alpharma Inc. is submitting a separate Answer.

that it is answering Plaintiff's allegations solely on behalf of itself, even when Plaintiff's allegations refer to alleged conduct by Purepac and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, Purepac's failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or Purepac shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

Purepac denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos, or speculation contained in any particular averment or in the Complaint as a whole. In addition, Purepac specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Purepac has included in this Answer and Affirmative Defenses certain captions used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, those captions.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

### **SPECIFIC RESPONSES**

1. Purepac admits that the State of Iowa (the "State") seeks to bring this action as alleged in Paragraph 1 of the Complaint, but Purepac denies that there is any basis for the State to do so and denies that the State is entitled to any relief.

2. To the extent the allegations in Paragraph 2 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “purposefully report[s] false and inflated price information.” To the extent the allegations in Paragraph 2 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

3-4. To the extent the allegations in Paragraphs 3-4 are directed at Purepac, Purepac denies them. Purepac specifically denies that it submits “false and inflated pricing information in order to ‘create a spread.’” Purepac further denies the characterization of “spread” in Paragraphs 3-4. To the extent the allegations in Paragraphs 3-4 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

5. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. To the extent the allegations in Paragraph 6 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “purposefully manipulate[s] a market that, by defendants’ own design, is extremely complicated and non-transparent.” To the extent the allegations in Paragraph 6 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

7-8. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 7-8.

9. To the extent the allegations in Paragraph 9 are directed at Purepac, Purepac denies them. Purepac specifically denies that it engages in any “unlawful price

reporting activity [that] infects all four [pricing] benchmarks and renders each of them false and inflated.” To the extent the allegations in Paragraph 9 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

10. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, except that it admits that it pays Medicaid rebates to Iowa and that such rebates lower the price Iowa Medicaid pays for Purepac’s prescription drugs. To the extent the allegations in Paragraph 10 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

11. To the extent the allegations in Paragraph 11 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 11 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

12. To the extent the allegations in Paragraph 12 are directed at Purepac, Purepac denies them. Purepac specifically denies that it engages in “unlawful pricing schemes,” the “manipulation of the Medicaid program” or the “improper reporting of false and inflated pricing information” resulting in “overcharges . . . to the Iowa Medicaid Program.” To the extent the allegations in Paragraph 12 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

13. To the extent the allegations in Paragraph 13 are directed at Purepac, Purepac denies them. Purepac specifically denies that it engages in “wrongful practices”

that have a “pernicious . . . effect on the public fisc.” To the extent the allegations in Paragraph 13 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

14-15. Purepac admits that it voluntarily participates in the Iowa Medicaid program, but denies that it has violated any State or Federal law. To the extent the allegations in Paragraphs 14-15 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 14-15 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied. Purepac denies all other allegations in Paragraphs 14-15.

16. To the extent the allegations in Paragraph 16 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “intentionally report[s] false prices to the government.” To the extent the allegations in Paragraph 16 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

17. To the extent the allegations in Paragraph 17 are directed at Purepac, Purepac denies them. Purepac specifically denies that it engages in “fraudulent, unfair and deceptive practices.” To the extent the allegations in Paragraph 17 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

18. Purepac admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiff with respect to any such NDCs. To the extent the allegations in Paragraph 18 are directed at parties

other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. Purepac denies all other allegations in Paragraph 18.

19. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19. To the extent the allegations in Paragraph 19 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

20. To the extent that the allegations in Paragraph 20 are directed at Purepac, Purepac denies them, except Purepac admits that it manufactures and sells prescription drugs and that it participates in the Iowa Medicaid Program. To the extent the allegations in Paragraph 20 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

21. Purepac admits that it conducts business in the State of Iowa.

22. The allegations in Paragraph 22 are directed to other Defendants and require no response from Purepac. To the extent a response is deemed to be required, Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22.

23. With respect to the allegations in Paragraph 23 (a)-(b), plaintiff improperly refers to two defendants as “the ALPHARMA GROUP OR ALPHARMA,” and therefore Purepac denies this introductory clause. With respect to subparagraph (a) Purepac lacks knowledge or information sufficient to form a belief as to the truth of the allegations. With respect to subparagraph (b), Purepac denies that defendant Purepac Pharmaceutical Co. (“Purepac”) is a wholly owned subsidiary of Alharma Inc. Purepac states that Alharma Inc. did acquire Purepac in December 2001 and further states that on

December 19, 2005, Alpharma Inc. sold its generics pharmaceutical business, including Purepac, to Actavis Group hf. Purepac further states that the principal place of business of Actavis Elizabeth LLC, Purepac's new name, is 200 Elmora Avenue, Elizabeth, NJ 07202. Purepac otherwise denies the allegations in Paragraph 23 (a)-(b).

24-58. The allegations in Paragraphs 24-58 are directed to other Defendants and require no response from Purepac. To the extent a response is deemed to be required, Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 24-58.

59. Purepac admits that the State seeks to bring this action as alleged in Paragraph 59, but Purepac denies there is any basis for the State to do so and denies that the State is entitled to any relief.

60-61. Paragraphs 60-61 state legal conclusions as to which no response is required. To the extent a response is required, Purepac denies the allegations in Paragraphs 60-61, and notes that this captioned matter has been transferred to this Court by the Judicial Panel on Multi District Litigation, pursuant to 28 U.S.C. § 1407.

62. With respect to the allegations in Paragraph 62, Purepac admits that Medicaid was established by Title XIX of the Social Security Act. Purepac further states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

63. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63, except Purepac admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 63 refer to statutes or

regulations, those sources speak for themselves, and any characterizations thereof are denied.

64-65. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 64-65. To the extent the allegations in Paragraphs 64-65 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

66. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66, except it admits that national drug codes are assigned to prescription drugs.

67. To the extent the allegations in Paragraph 67 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Purepac otherwise denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67.

68. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68. To the extent the allegations in Paragraph 68 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

69. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69. To the extent the allegations in Paragraph 69 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

70. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70.



71-72. To the extent the allegations in Paragraphs 71-72 are directed at Purepac, Purepac denies them. Purepac further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 71-72 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

73-80. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 73-80 or their subsections. To the extent the allegations in Paragraphs 73-80 or their subsections refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

81. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81, except that it admits that pricing compendia such as First DataBank and Medi-Span have published AWP's and FUL's, and denies that Purepac has any control over such prices.

82. To the extent the allegations in Paragraph 82 are directed at Purepac, Purepac denies them. Purepac specifically denies that it "purposefully and fraudulently conceal[s]" the "true prices" of its drugs by "claiming they are proprietary trade secrets." To the extent the allegations in Paragraph 82 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

83. Purepac denies having knowledge or information sufficient to form a

belief as to the truth of the allegations in Paragraph 83.

84. To the extent the allegations in Paragraph 84 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “fraudulently misrepresent[s]” its true prices or that it reports “false and inflated prices.” To the extent the allegations in Paragraph 84 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

85. To the extent the allegations in Paragraph 85 are directed at Purepac, Purepac denies them, except that Purepac admits that Exhibit A purports to identify total expenditures by Defendant. Purepac specifically denies any “unfair practices, deception, and fraud.” To the extent the allegations in Paragraph 85 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

86. To the extent the allegations in Paragraph 86 are directed at Purepac, Purepac denies them. Purepac specifically denies conducting any “fraudulent practices.” To the extent the allegations in Paragraph 86 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

87-89. To the extent the allegations in Paragraphs 87-89 are directed at Purepac, Purepac denies them. Purepac specifically denies that it reports “false and inflated” “WACs or WAC equivalents.” To the extent the allegations in Paragraphs 87-89 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

90-92. To the extent the allegations in Paragraphs 90-92 are directed at Purepac, Purepac denies them. Purepac further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 90-92 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

93-98. To the extent the allegations in Paragraphs 93-98 are directed at Purepac, Purepac denies them, except Purepac admits that it has provided the list prices of drugs to certain industry pricing compendia and that publishers apply their own markups to the list prices. Purepac specifically denies that it “either report[s] or caused to be reported false and inflated AWP,” “false WAC or WAC equivalents,” or that Purepac “alone control[s] the false and inflated AWP that are published for [its] drugs.” To the extent the allegations in Paragraphs 93-98 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

99. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99.

100. To the extent the allegations in Paragraph 100 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 100 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

101. The allegations in Paragraph 101 or the exhibit referenced therein require no response from Purepac on the grounds that exhibit C does not name any Purepac drugs. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are

directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

102-108. To the extent the allegations in Paragraph 102-108 are directed at Purepac, Purepac denies them, except Purepac admits that CMS has established FULs for certain drugs. To the extent the allegations in Paragraph 102-108 refer to statutes or regulations, Purepac respectfully refers the Court to those statutes or regulations, and any characterization thereof is denied. To the extent the allegations in Paragraphs 102-108 are directed at parties other than Purepac, Purepac lacks knowledge or information sufficient to form a belief as to their truth.

109. The allegations in Paragraph 109 require no response from Purepac on the grounds that the Iowa SMAC claims have been dismissed by the Court. To the extent a response is required, Purepac denies the allegations in Paragraph 109.

110-132. To the extent the allegations in Paragraphs 110-132 are directed at Purepac, Purepac denies them, except Purepac admits that it has executed a rebate agreement with HHS. To the extent the allegations in Paragraphs 110-132 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 110-132 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

133. To the extent the allegations in Paragraph 133 are directed at Purepac, Purepac denies them. Purepac specifically denies that it has participated in any “pricing scheme . . . by exacerbating the complexities of the . . . drug market.” To the extent the

allegations in Paragraph 133 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

134. To the extent the allegations in Paragraph 134 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “purposefully conceal[s its] true prices.” To the extent the allegations in Paragraph 134 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 134 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

135. To the extent the allegations in Paragraph 135 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 135 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

136. To the extent the allegations in Paragraph 136 are directed at Purepac, Purepac denies them, except Purepac admits that certain of its contracts are subject to confidentiality agreements and that Purepac does offer discounts to certain of its customers. To the extent the allegations in Paragraph 136 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

137. To the extent the allegations in Paragraph 137 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “obscure[s] the true prices for [its] drugs with [its] policy of treating different classes of trade differently.” To the

extent the allegations in Paragraph 137 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

138-139. To the extent the allegations in Paragraphs 138-139 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “maintain[s] two sets of pricing records: one with . . . inflated prices and another with . . . actual prices.” To the extent the allegations in Paragraphs 138-139 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 138-139 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

140-141. To the extent the allegations in Paragraphs 140-141 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “hide[s its] real drugs prices by secretly providing free drugs and phony grants” or that it conceals its true prices “to create spreads between actual cost and reimbursement amounts . . . to influence market share.” To the extent the allegations in Paragraphs 140-141 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

142. To the extent the allegations in Paragraph 142 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 142 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

143. To the extent the allegations in Paragraph 143 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 143 are directed at

parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

144-145. To the extent the allegations in Paragraphs 144-145 are directed at Purepac, Purepac denies them. Purepac specifically denies that it has engaged in any “unlawful and undisclosed manipulation of the price reporting system” or caused the “publication of a false WAC,” AWP, or FUL. To the extent the allegations in Paragraphs 144-145 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

146. To the extent the allegations in Paragraph 146 are directed at Purepac, Purepac denies them. Purepac specifically denies that it has “caus[ed] false prices to be published.” To the extent the allegations in Paragraph 146 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

147. To the extent the allegations in Paragraph 147 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “submit[s] false and inflated wholesale price information in order to create a spread.” Purepac further denies the characterization of “spread” in Paragraph 147. To the extent the allegations in Paragraph 147 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

148. To the extent the allegations in Paragraph 148 are directed at Purepac, Purepac denies them. Purepac specifically denies that it has “corrupted the market for prescription drugs” or has “deliberately sought to create a powerful financial incentive for providers to prescribe drugs based primarily on the spread.” Purepac further denies the

characterization of “spread” in Paragraph 148. To the extent the allegations in Paragraph 148 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

149-150. To the extent the allegations in Paragraphs 149-150 are directed at Purepac, Purepac denies them. Purepac specifically denies that it “market[s its] products based on the spread between reimbursement (based on AWP, WAC, or a WAC equivalent) and actual acquisition cost” or that it “compete[s] on reimbursement and profit rather than cost.” To the extent the allegations in Paragraphs 149-150 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

151-152. To the extent the allegations in Paragraphs 151-152 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraphs 151-152 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 151-152 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

153-154. To the extent the allegations in Paragraphs 153-154 are directed at Purepac, Purepac denies them. Purepac specifically denies that it has “intentionally manipulat[ed] the nation’s drug reimbursement system . . . with false and inflated prices.” To the extent the allegations in Paragraphs 153-154 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

155-157. To the extent the allegations in Paragraphs 155-157 are directed at



Purepac, Purepac denies them. Purepac specifically denies that it reports “reimbursement prices . . . to the publishing compendia” or that it engages in “purposeful AWP manipulation.” To the extent the allegations in Paragraphs 155-157 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 155-157 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

158. To the extent the allegations in Paragraph 158 are directed at Purepac, Purepac denies them. Purepac specifically denies that it reports “price information that . . . does not comply with the HHS OIG’s guidelines” by not accounting for various types of discounts. To the extent the allegations in Paragraph 158 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

159-165. Purepac denies having knowledge or information to form a belief as to the truth of the allegations in Paragraphs 159-165, except Purepac admits that it participates in the Federal Medicaid Rebate Program through which Iowa Medicaid is obligated to reimburse providers for Purepac drugs. To the extent the allegations in Paragraphs 159-165 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

166. To the extent the allegations in Paragraph 166 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 166 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

167-171. To the extent that the allegations in Paragraphs 167-171 are directed at Purepac, Purepac denies them, except Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegation that the “Iowa Medicaid Program spent over \$1.6 billion for defendants’ drugs between 1992 and 2005 alone.” Purepac specifically denies that it “knowingly interfered with Iowa’s ability to reimburse providers at EAC.” To the extent the allegations in Paragraphs 167-171 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

172-177. With respect to the allegations in Paragraphs 172-177, Purepac admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 172-177 or Exhibit B are directed at Purepac, Purepac denies them. Purepac specifically denies that it “routinely submitted false prices” to pricing compendia. Purepac further denies the characterization of “spread” in Paragraphs 172-177 and Exhibit B. To the extent the allegations in Paragraphs 172-177 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

178. To the extent the allegations in Paragraph 178 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 178 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

179. To the extent the allegations in Paragraph 179 are directed at Purepac, Purepac denies them, except Purepac admits that many of its contracts with purchasers

included discounts. To the extent the allegations in Paragraph 179 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

180. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

181-200. The allegations in Paragraphs 181-200 are directed to other Defendants and require no response from Purepac. To the extent a response is deemed to be required, Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 181-200.

201. Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 201 or its footnote or exhibit referenced therein.

202-203. Purepac denies the allegations in Paragraphs 202-203 and the exhibit referenced therein.

204. Purepac admits that it has been sued by Florida. Purepac respectfully refers the Court to the pleadings in that action, and any characterization thereof is denied.

205. Purepac denies the allegations in Paragraph 205.

206-613. The allegations in Paragraphs 206-613 are directed to other Defendants and require no response from Purepac. To the extent Paragraph 585 references Purepac, the allegations in that paragraph are denied. To the extent a response is deemed to be

required to the remaining paragraphs, Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 206-613.

614-616. To the extent the allegations in Paragraphs 614-616 are directed at Purepac, Purepac denies them, except Purepac denies having knowledge or information sufficient to form a belief as to the truth of the allegation that Iowa's Medicaid program "spent over \$1.6 billion for defendants' drugs in state and federal dollars from 1992-2005 alone." Purepac specifically denies that it was involved in any "false price reporting scheme" or "misconduct," or that it has been "unjustly enriched." To the extent the allegations in Paragraphs 614-616 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

617-632. To the extent the allegations in Paragraphs 617-632 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraphs 617-632 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 630 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

## **COUNT I**

### **VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

633. In response to Paragraph 633, Purepac repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1-632.

634-642. To the extent the allegations in Paragraphs 634-642 are directed at Purepac, Purepac states that the Court has dismissed the claim to which these allegations

relate. To the extent that a response is still required, Purepac denies the allegations. To the extent the allegations in Paragraphs 634-642 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

## **COUNT II**

### **BREACH OF CONTRACT**

643. In response to Paragraph 643, Purepac repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1-642.

644-651. To the extent the allegations in Paragraphs 644-651 are directed at Purepac, Purepac states that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Purepac denies the allegations. To the extent the allegations in Paragraphs 644-651 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth.

## **COUNT III**

### **IOWA CONSUMER FRAUD ACT**

**(Iowa Code § 714.16)**

652. In response to Paragraph 652, Purepac repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1-651.

653. To the extent the allegations in Paragraph 653 and the exhibits referenced therein are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraph 653 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the

allegations in Paragraph 653 refers to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

654-657. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto refer to statutes, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto contain legal conclusions, no response is required but the allegations are denied.

#### **COUNT IV**

#### **FRAUD**

658. In response to Paragraph 658, Purepac repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1-657.

659-662. To the extent the allegations in Paragraphs 659-662 and the exhibits referenced therein are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraphs 659-662 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 659-662 refer to Iowa law, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 659-662 contain legal conclusions, no response is required but the allegations are denied.

## **COUNT VIII**

### **UNJUST ENRICHMENT**

663. In response to Paragraph 663, Purepac repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1-662.

664-666. To the extent the allegations in Paragraphs 664-666 are directed at Purepac, Purepac denies them. To the extent the allegations in Paragraphs 664-666 are directed at parties other than Purepac, Purepac denies having knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 664-666 contain legal conclusions, no response is required but the allegations are denied.

667-675. Purepac denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 667-675 of the Complaint.

**WHEREFORE**, Purepac demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

### **AFFIRMATIVE DEFENSES**

Purepac reasserts and incorporates herein by reference the assertions of Paragraphs 1-675 hereof.

#### **First Affirmative Defense**

Plaintiff fails to state a claim against Purepac upon which relief may be granted.

**Second Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because it did not rely on any alleged misrepresentations or fraud by Purepac. Plaintiff knew that providers could obtain Purepac drugs at prices below AWP.

**Third Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

**Fifth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the state action doctrine.

**Sixth Affirmative Defense**

To the extent Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Purepac based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition against double recovery for the same injury.

**Seventh Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine.



**Eighth Affirmative Defense**

Plaintiff's claims against Purepac are barred, in whole or in part, because Purepac did not make any false statements to the Plaintiff. As to any statement asserted against Purepac that Plaintiff alleges to be false or misleading, Purepac had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Ninth Affirmative Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, and the Prescription Drug, Improvement and Modernization Act of 2003, including all amendments to the same and all regulations promulgated thereunder.

**Tenth Affirmative Defense**

Plaintiff's claims against Purepac are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

**Eleventh Affirmative Defense**

Plaintiff fails to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Purepac.

**Twelfth Affirmative Defense**

Any and all actions taken by Purepac with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Thirteenth Affirmative Defense**

Purepac's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

**Fourteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a consumer within the meaning of the Iowa Consumer Fraud Act.

**Fifteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a person within the meaning of the Iowa Consumer Fraud Act.

**Sixteenth Affirmative Defense**

Some or all of Plaintiff's claims against Purepac arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**Seventeenth Affirmative Defense**

Purepac denies that Plaintiff has a valid consumer protection claim against Purepac under the Iowa Consumer Fraud Act. However, if such claim is found to exist, Purepac pleads all available defenses under the Act.

**Eighteenth Affirmative Defense**

To the extent that Plaintiff attempts to seek equitable relief against Purepac, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

**Nineteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

**Twentieth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Purepac after the filing of the Complaint.

**Twenty-First Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Twenty-Second Affirmative Defense**

Plaintiff's claims against Purepac are barred, in whole or in part, due to their failure to join indispensable parties.

**Twenty-Third Affirmative Defense**

Plaintiff's claims against Purepac are barred, in whole or in part, because Plaintiff has not suffered damages as a result of the matters alleged in the Complaint.

**Twenty-Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages, and that failure to mitigate damages should proportionately reduce the

recovery of such persons and the allocation of any fault, if any exists, attributable to Purepac; (2) because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; and (3) because damages are speculative and remote and because of the impossibility of ascertaining and allocating alleged damages.

**Twenty-Fifth Affirmative Defense**

Purepac is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Twenty-Sixth Affirmative Defense**

Plaintiff's claims against Purepac are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Iowa Constitution.

**Twenty-Seventh Affirmative Defense**

Plaintiff's claims against Purepac are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

**Twenty-Eighth Affirmative Defense**

Plaintiff's claims against Purepac are barred, in whole or in part, because they violate Purepac's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Iowa Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Twenty-Ninth Affirmative Defense**

Plaintiff fails to allege facts or a cause of action sufficient to support a claim against Purepac for compensatory damages, attorneys' fees, enhanced damages, treble damages and/or legal fees or costs.

**Thirtieth Affirmative Defense**

The claims alleged herein, based on the facts alleged, are barred in whole or in part by Plaintiff's own negligence or gross negligence and the doctrines of comparative or contributory negligence.

**Thirty-First Affirmative Defense**

Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because Purepac did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

**Thirty-Second Affirmative Defense**

Plaintiff has failed to plead with particularity allegations of fraud by Purepac contained in the Complaint.

**Thirty-Third Affirmative Defense**

Plaintiff's claims for fraud and fraudulent concealment are barred because the Plaintiff cannot predicate a claim for fraud on reliance by a third party.

**Thirty-Fourth Affirmative Defense**

Plaintiff's claims against Purepac are barred because Plaintiff lacks standing or capacity to bring the some or all of the claims asserted against Purepac under Iowa law.

**Thirty-Fifth Affirmative Defense**

Plaintiff's claims against Purepac are barred in whole or in part by the doctrine of voluntary payment.

**Thirty-Sixth Affirmative Defense**

Plaintiff's claims against Purepac for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Thirty-Seventh Affirmative Defense**

Plaintiff's claims against Purepac for unjust enrichment are barred because the Complaint does not allege that Defendants received any payment or property from the Plaintiff.

**Thirty-Eighth Affirmative Defense**

Plaintiff's claims against Purepac for injunctive relief against Purepac are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Thirty-Ninth Affirmative Defense**

Plaintiff's claims against Purepac are misjoined with Plaintiff's claims against other Defendants and must be severed.

**Fortieth Affirmative Defense**

Any damages recovered by the Plaintiff must be limited by any applicable statutory ceiling on recoverable damages.

**Forty-First Affirmative Defense**

To the extent punitive damages are sought, Plaintiff's punitive damages claims against Purepac (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Purepac; (3) cannot be sustained because the laws regarding the standards for determining liability for, and the amount of, punitive damages fail to give Purepac prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Purepac's due process rights guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Purepac's due process and equal protection rights guaranteed by the Fifth, Eighth and Fourteenth Amendments to the United States Constitution and be improper under the Iowa Constitution and Iowa common law.

**Forty-Second Affirmative Defense**

Plaintiff fails to allege facts or a cause of action against Purepac sufficient to support a claim for prejudgment interest or any other relief.

**Forty-Third Affirmative Defense**

Plaintiff has not suffered, and will not suffer, any injuries to a legally protected or cognizable interest by reason of the conduct of Purepac as alleged in the Complaint.

**Forty-Fourth Affirmative Defense**

Purepac hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its Answer to assert such defense.

**Forty-Fifth Affirmative Defense**

Plaintiff's claims against Purepac are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superseding conduct of third parties.

**Forty-Sixth Affirmative Defense**

Purepac adopts by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

Respectfully submitted,

Dated: September 18, 2008	<u>/s/ John R. Fleder</u> John R. Fleder <b>HYMAN, PHELPS, &amp; MCNAMARA, P.C.</b> 700 Thirteenth Street NW Suite 1200 Washington DC 20005 (202)-737-5600  Counsel for Defendant Purepac Pharmaceutical Co.
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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF PUREPAC PHARMACEUTICAL CO. TO THE STATE OF IOWA'S COMPLAINT was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

September 18, 2008

/s/ J.R. Fleder  
John R. Fleder